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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,698	04/26/2005	Nicolai Agger	P07181US00	8742
22885 7590 01/10/2008 MCKEE, VOORHEES & SEASE, P.L.C. 801 GRAND AVENUE SUITE 3200 DES MOINES, IA 50309-2721			EXAMINER CLARK, AMY LYNN	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 01/10/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/532,698

Applicant(s)

AGGER, NICOLAI

Examiner

Amy L. Clark

Art Unit

1655

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-11 and 13-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-11 and 13-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 October 2007 has been entered.

Claims 1, 2, 5-11 and 13-23 are currently pending and currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5-11 and 13-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claims 1 and 2 are rendered uncertain by the phrase "and from 20-80% by weight of a mixture of at least one carbohydrate and further comprising electrolytes" because it is unclear if the composition comprises 20-80% by weight of a mixture a carbohydrate **and** electrolytes or if the composition comprises 20-80% by weight of a carbohydrate and that the total composition comprising Isphagula

Husk, at least one amino acid and a carbohydrate further comprises electrolytes. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 9 are rendered uncertain by the phrase "processed from a lactic yeast source" because, first of all, it is unclear as to what Applicant means by "lactic yeast". Does Applicant mean that the yeast is grown on milk or that the yeast produces lactic acid? What is a lactic yeast source? Is that the medium on which the yeast is grown or does that mean the lactic yeast itself? Secondly, does Applicant mean that the amino acids themselves are processed or does Applicant mean that the amino acids are obtained from lactic yeast that has been processed or does Applicant mean that the amino acids are obtained from a source of lactic yeast, wherein the source has been processed? The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The term "natural" in claim 23 is a relative term which renders the claim indefinite. The term "natural" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What is "natural" vitamin E? Is this vitamin E found in nature or does it mean unprocessed vitamin E or does it mean vitamin E itself? The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim Rejections - 35 USC § 103

Claims 1, 2, 5-11 and 13-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gjerløv (N, WO 85/01441 A1), in view of Simone (A*, US Patent Number 5,397,786), "Always your Choice: Diarrhea-Nutritional Management" (U), http://web.archive.org/web/*/http://www.gatorade.com/ (V) and Nakagaki (O, JP 08-038046 A, Translation provided herein).

Gjerløv teaches a specific composition for both rehydrating a monogastric animal and which stops diarrhoea (which is an alternative spelling of diarrhea) comprising glucose, citric acid, potassium chloride, sodium citrate, sodium chloride, sodium bicarbonate (which are all electrolytes), terra rubrum, which is a coloring agent, wheat bran, which is a filler and is a fibrous bran material, and Isophogla husk, which is the dried seed coats of *Plantago ovata* (See page 11 and also page 12, Examples 1 and 2). Gjerløv further teaches the composition may comprise electrolytes in an amount of 40-60% by weight, fibre (which is an alternative spelling of fiber) from dried, crushed seed coats of *Plantgo ovata*, which is synonymous with Isphagula Husk, in an amount of 20-70% by weight, fillers (roughage), such as fibrous wheat bran, taste corrigents and coloring agents (See abstract), and that the composition should be administered in the form of a beverage (See page 11 and also page 12, Examples 1 and 2). Please note that electrolytes, by definitions, replace salts lost by the body through excessive fluid loss (such as via vomiting, sweating, diarrhea, etc.).

Simone teaches a rehydration drink for people who work under severe conditions, are athletes and patients who exhibit dehydration from diarrhea or vomiting,

comprising 1-35 milligrams of at least one carbohydrate, such as glucose (See column 2, lines 45-48, 64 and 65), electrolytes in an amount of 2 to 2500 milligrams, such as sodium chloride and potassium chloride (See column 3, lines 5 and 9), at least one ammonia neutralizer, in the form of an amino acid, in an amount of 0.1 to 750 milligrams, such as glutamine (See column 3, lines 21-28), and at least one antioxidant, such as vitamin E (See Abstract). Please note that electrolytes, by definitions, replace salts lost by the body through excessive fluid loss (such as via vomiting, sweating, diarrhea, etc.).

"Always your Choice: Diarrhea-Nutritional Management" teaches that Gatorade is a fluid and electrolyte replacement supplement that works well for people with diarrhea (See page 1). "Always your Choice: Diarrhea-Nutritional Management" further teaches that glutamine is an amino acid that gets used up during gastrointestinal distress and that adding glutamate back to the gut helps feed the gut cells and repair damage, thereby helping with digestion and absorption (See page 3).

http://web.archive.org/web/*/http://www.gatorade.com/ teaches that Gatorade contains glucose-fructose syrup, sodium citrate, citric acid (both are electrolytes) and Red 40, which is synonymous with FD&C RED #40, and is a known food coloring agent.

Nakagaki teaches a spawn for fermented milk and fermented milk produced by the spawn, wherein the spawn comprises a yeast fungus and wherein the fermented milk, which reads on a lactic yeast source, prevents and treats diarrhea.

Although Nakagaki does not teach that an amino acid, such as glutamine, is processed from a lactic yeast source, the claimed functional properties are intrinsic to

the preparation taught by Nakagaki because the ingredients taught by Nakagaki are one and the same as disclosed in the instantly claimed invention of Applicant and because glutamine is prevalent in milk and milk is known to be a good source of glutamine. Therefore, the fermented milk taught by Nakagaki intrinsically contains glutamine and glutamine would thereby be intrinsic to milk fermented with lactic yeast.

Gjerløv does not teach that a composition comprising Isphagula husk, at least one carbohydrate and electrolytes further comprises at least one amino acid, such as glutamine, nor does Gjerløv teach an amino acid processed form a lactic yeast source, nor does Gjerløv teach a composition further comprising alpha tocopherol (vitamin E). However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the composition taught by Gjerløv to provide the instantly claimed invention because at the time the invention was made it would have been obvious to combine the ingredients of a composition for rehydrating monogastric animals and for stopping diarrhea, which reads on treating diarrhea, suffering from diarrhea, including human beings, wherein the composition comprises glucose, citric acid, potassium chloride, sodium citrate, sodium chloride, sodium bicarbonate (which are all electrolytes), terra rubrum, which is a coloring agent, wheat bran, which is a filler and is a fibrous bran material, and Isophogla husk, which is the dried seed coats of *Plantago ovata*, taught by Gjerlov, with amino acids, such as glutamine, and at least one antioxidant, such as vitamin E taught by Simone, ingredients found in Gatorade, such as glucose-fructose syrup, sodium citrate, citric acid (both are electrolytes) and

Red 40, which is synonymous with FD&C RED #4 and also glutamine because glutamine is an amino acid that gets used up during gastrointestinal distress and that adding glutamate back to the gut helps feed the gut cells and repair damage, as taught by "Always your Choice: Diarrhea-Nutritional Management" and http://web.archive.org/web/*/http://www.gatorade.com/ and it would have been obvious to use fermented milk, which reads on a lactic yeast source, because fermented milk is known to prevent and treat diarrhea, as taught by Nakagaki. Furthermore, one of ordinary skill in the art would have reasonable expectation of success in using such a composition for treating diarrhea and rehydrating a monogastric animal suffering from diarrhea because the beneficial properties of the claimed ingredients for this purpose are taught by the cited references.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients, each of which is taught by the prior art, to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant argues that even looking at the broadest composition claim 1, it requires 5-30% Isphagula Husk, 1-20% amino acid, and 20-80% of a mixture of at least one carbohydrate and electrolytes, that Gjerlov, which is licensed to the assignee, represented the starting point for the present invention and what is missing from Gjerlov, and unexpected is the amino acid and Isphagula Husk advance cell growth and thus repair to treat diarrhea more than either alone and that it therefore represents the classic case of the combination exceeding the sum of its parts.

However, this is not found persuasive because amino acids, such as glutamine, are known in the art to be administered to monogastric animals to treat diarrhea and symptoms of diarrhea, such as dehydration, as clearly shown above. Furthermore, the teachings of Simone provides a composition for treating a person suffering from dehydration caused by diarrhea, wherein the composition comprises the claimed amounts of amino acids, such as glutamine, in combination with the claimed amount of electrolytes. Therefore, the combination of these amounts of each ingredient was already known in the art. It was also known that all of the ingredients in the compositions claimed by Applicant all have the same functional effect. Furthermore, all

of the claimed ingredients were also taught in the art in the amounts claimed by Applicant. Therefore, the references, in combination and individually, teach that the amounts of each ingredient claimed by Applicant are useful for the same purpose claimed by Applicant and the rejection remains.

Response to Arguments

Claim Rejections - 35 USC § 112

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 October 2007, with respect to the rejection of claims 1, 2, 5-11 and 13-23 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement have been fully considered and are persuasive based upon Applicant's amendments to the claims to provide an enabled intended use. Therefore, to the rejection of claims 1, 2, 5-11 and 13-23 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been withdrawn.

Claim Rejections - 35 USC § 103

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 October 2007, with respect to the rejection of claims 1, 2, 5-11 and 13-23 under 35 U.S.C. 103(a) as being unpatentable over Gjerlov (B*, US Patent Number 5,038,396), in view of Simone (A*, US Patent Number 5,397,786) have been

fully considered and are not found to be persuasive; however, the Examiner has newly applied a patent issued to Gjerløv (N, WO 85/01441 A1) that better describes the invention disclosed in the previously cited US patent issued to Gjerløv (B*, US Patent Number 5,038,396), so the Examiner is now providing this reference in the stead of the previously Applied Gjerløv reference. Therefore, the rejection has been withdrawn. Upon further consideration, a new ground of rejection is made of claims 1, 2, 5-11 and 13-23 under 35 U.S.C. 103(a) as being unpatentable over Gjerløv (N, WO 85/01441 A1), in view of Simone (A*, US Patent Number 5,397,786), "Always your Choice: Diarrhea-Nutritional Management" (U), http://web.archive.org/web/*/http://www.gatorade.com/ (V) and Nakagaki (O, JP 08-038046 A, Translation provided herein). Since the newly applied Gjerløv references teaches all of the limitations previously taught in the originally applied Gjerløv patent, and since Simone is being reapplied, Applicants arguments have been addressed above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

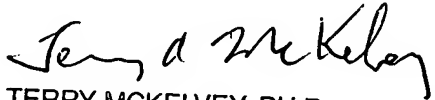
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Amy L. Clark
AU 1655

Amy L. Clark
December 31, 2007


TERRY MCKELVEY, PH.D.
SUPERVISORY PATENT EXAMINER